Do working alliance, patient outcome expectations and self-efficacy predict response to treatment for Achilles tendinopathy: protocol for a longitudinal cohort study (MAP II study)

Introduction

Pain related to a tendon, termed tendinopathy, can be traumatic or insidious in onset and short-lasting or persistent in nature (1). Tendinopathy is common musculoskeletal condition; the incidence of tendinopathy is higher than osteoarthritis, for example (2). Achilles tendinopathy (AT) affects both active and sedentary individuals and can be characterised by reduced activity tolerance to specific tasks that load the tendon (3). This results in decreased activity participation such as walking, running and working (4).

Current clinical guidelines recommend exercise as the first line treatment for people with Achilles tendinopathy (5). However, the rate and extent of improvement in pain and disability varies (6). This variation suggests we need to understand what factors predict change so we can enhance our care. Previously it was suggested that exercise worked by improving the strength or structure of the tendon, but it has been reported that pain and disability can change without corresponding changes in strength or structure (7). This suggests that other factors might be important predictors.

Recent literature suggests cognitive and contextual influences such as self-efficacy, working alliance and expectations may be important factors for predicting change in pain and disability in tendinopathy and need investigation (6,8). Based on this need, high-quality research is warranted. To inform the development of this research, two recent studies have been undertaken. Firstly, a feasibility study was completed. This study aimed to understand if it was feasible to collect data using a secure website to explore the association and predictive relationship of working alliance, outcome expectations and self-efficacy with pain and disability in the management of AT (9). The second study was a process evaluation to gain insight into the procedures undertaken in the feasibility study (10). Seven patients were interviewed to discover what worked (and did not) from their perspective during the study. Based on the results from the feasibility study and the information from the interviews with patients,

using this website is feasible, but we have made some changes before proposing this larger study. These changes include better promotion of the study, how verbal recruitment strategies could be improved, and how communication between clinicians and researchers could be made better. Based upon this knowledge this proposal aims to understand if working alliance, patient outcome expectations and self-efficacy predict response to treatment for AT.

Design

A multi-centre, prospective cohort study

Setting

Participants will be recruited from physiotherapy services across the UK. Seven sites have expressed interest, providing an expected referral rate of 1750 people with AT over a twelve-month period.

Recruitment

Patients diagnosed with AT by their treating physiotherapist will be introduced to the study through a verbal discussion and then provision of a card detailing the study's website (www.managing-achilles-pain.com). If the consultation is over telephone or via video-link, the physiotherapist will forward the study details via email. The website hosts password protected information (the participant information sheet, consent form and the clinical outcome measures and predictive factors). The participant can freely read the participant information sheet and consent details without time constraint, and decide to participate or not. The flow of a participant through the study is described in figure 1.

Diagnosis of AT will be based on criteria from expert consensus: local Achilles tendon pain reproduced with load-based activity and tenderness on palpation (5). Prior to commencing recruitment, physiotherapists will receive a training package. This training is important to maximise physiotherapists investment in the study, and help them answer any immediate questions from participants (10). Training will be delivered by AM & SO'N using online resources and face-to-face, if requested and safe to do so. The training will ensure physiotherapists are familiar with the background, aim and processes of the study, as well as criteria for inclusion. Hence,

recruitment to this proposed study and subsequent data collection will not be restricted by limitations imposed by COVID-19.

Inclusion and exclusion criteria

For participants to be included in the study they are required to:

- be a minimum of 18 years old
- have access to the internet
- have an available email address
- to have support in place to understand written English if it is required
- be diagnosed with AT by their treating physiotherapist
- be undertaking treatment prescribed by a physiotherapist.

Participants will be excluded from the study if they have:

- not provided informed consent
- been diagnosed with Achilles tendon tear/rupture
- received surgery to the affected Achilles tendon
- pain in the Achilles region with movements of the spine or neural tissue.

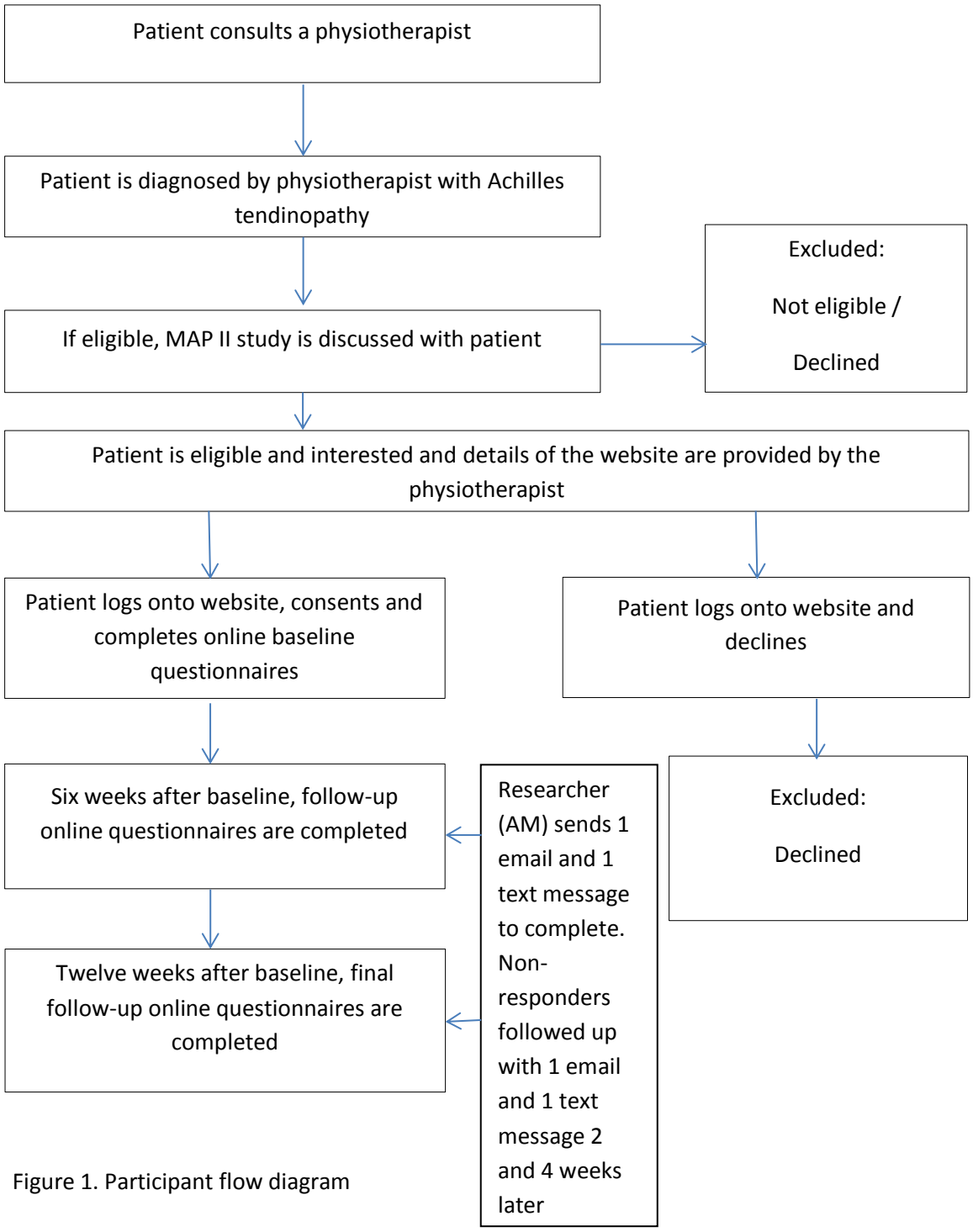

Figure 1. Participant flow diagram

Care Pathways

The effect of treatment is not under examination; the care pathway for recruited patients will not change.

Ethical approval

HRA approval will be sought, along with approval from the relevant Research and Development departments at each site before research commences.

Patient and Public involvement

To inform this proposal, two preparatory studies have been undertaken which sought patients' and physiotherapists' involvement (9,10). Firstly, a feasibility study was completed. This study aimed to understand if it was feasible to collect data using a secure website to explore the association and predictive relationship of working alliance, outcome expectations and self-efficacy with pain and disability in the management of AT (9). Prior to commencement of the study, two patients were involved in the design of the website, the layout of the questionnaire and all other patient-facing material such as the participant information sheet used in this study. The second study was a process evaluation to gain insight into the procedures undertaken in the feasibility study (10). Seven patients were interviewed to discover what worked (and did not), from their perspective during the study. Based on the results from the feasibility study and the information from the interviews with patients, using this website is feasible, but we have made some changes before proposing this larger study. These changes include better promotion of the study, how verbal recruitment strategies could be improved, and how communication between clinicians and researchers could be made better.

To inform the development of this application, a Patient and Public involvement Group has been convened. The group consists of two people with Achilles tendinopathy and two members of the general public. Members of the group have reviewed the application for clarity of expression and readability. This has resulted in changes to the plain English Summary with the addition of bullet points and headings.

The group will continue to work with us for the duration of the project. We have budgeted for two further meetings over the duration of the project, and using guidance from the NIHR INVOLVE document 'budgeting for involvement', included £50 per person per meeting. To reduce burden, minimise risk relating to COVID-19 and maximise inclusivity of these meetings, members of the group can attend

virtually. Further advice will be sought into developing advertising, the participant information, the training provided for the physiotherapists, the communication of the project's progress (such as a newsletter) and on conclusions from any reports.

Predictors

The potential predictive factors will be self-reported using the secure website (www.managing-achilles-pain.com). These factors have been purposefully selected from prior research (6,8–10):

- Working Alliance measured by the Working Alliance Inventory Short-Form (WAI-SF) (11)
- Outcome expectation measured by the Global Rating of Change (12)
- Self-efficacy measured by the Pain Self-Efficacy Questionnaire (PSEQ) (13) .

Clinical outcomes

Changes in the self-reported measures of pain and disability will also be recorded using the website. Recent research has questioned the usefulness of the disease specific measure of disability, the Victorian Institute of Sports Assessment - Achilles (VISA-A) to accurately inform change in a patient's clinical status (14). Consequently, the primary clinical outcome measure will be the Lower Extremity Functional Score (LEFS) (15). The LEFS is recommended in current clinical guidelines to assess disability (5). Changes in self-reported pain will be measured the Numerical Pain Rating Scale (NPRS) (16).

Sample Size

With the significance level set at 5%, and adjusting for multiple testing, a sample size of 129 would provide more than 80% power to detect a minimum effect size of 0.3. Allowing for a 20% attrition rate, 159 participants will be recruited. The R project for statistical computing package (pwr.r.test) was used to calculate this sample size:

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> pwr.r.test (r=.3,sig.level=0.05/6, power=.8,alternative="two.sided")
    approximate correlation power calculation (arctangh transformation)
            n = 128.9428
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```
           r = 0.3
   sig.level = 0.008333333
       power = 0.8
 alternative = two.sided
```

Data Collection

Data from the clinical outcome measures and predictive factors will be collected on three occasions; at baseline, six weeks later and finally at twelve weeks following completion of the baseline questionnaire. A participant's email and telephone number will be collected at baseline and used to invite them to take the follow up questionnaires. To maximise response rates, non-responders will be sent one email and one text message reminder at two weeks and four weeks after an anticipated response.

Data analysis

A multiple linear regression is fitted for the clinical outcomes difference (12 weeks minus baseline) of LEFS and NPRS. Independent variables of the multiple linear regression are the predictor variables WAI-SF, GRC and PSEQ. Three predictor variables and two clinical outcome measures result in six hypothesis tests which are adjusted for multiple testing by the Bonferroni method.

Backward selection as secondary analysis is applied to analyse if collinearities impact the influence of the three predictors. Possible centre effects are investigated by fitting an additive centre effect and interaction effects using an analysis of covariance model.

Dissemination

The findings from this research may influence decision making between a physiotherapist and a patient. As such, patients and physiotherapists will be the target audiences to reach.

Dissemination to patients and physiotherapists will take place once the study is complete. To ensure it is effective and wide-reaching, despite the potential of an ongoing pandemic, we will use the study website to host a blog and a summary

infographic (which will be made available to download) detailing the findings of the research. These will be written using Plain English guidelines ensuring it is accessible to patients. To supplement this, but with the aim of providing more 'research-rich' detail, an online lecture will be developed and will be through YouTube. The link to the website and YouTube channel will be emailed to all participants and physiotherapists taking part in the research, as well as promoted on social media platforms such as Twitter. These online strategies will incur no additional costs to the project.

In addition to the online dissemination strategy, the research will be written up for publication in a journal with a high impact factor such as Physiotherapy. An abstract will also be submitted to the Physiotherapy UK conference, and other relevant National and International conferences such as Sports Kongress, for presentation.

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